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October 25, 1999

Dockets Management Branch
Division of Management Systems and Policy
Office of Human Resources and Management Services
Food and Drug Administration
5630 Fishers Lane, Room 1061, (HFA-305)
Rockville, MD 20852.

Gentlemen:

Reference : Docket No. 99D-2335

This letter is to request an extension to filing a response to this manual. We request this extension on the following basis:

1. ASTM is currently engaging in the consensus standard process which is to conclude in December, 1999 in New Orleans. The outcomes of these meetings could materially affect the comments we would make concerning the above referenced document.
2. The shelf study that is being conducted by the FDA regarding various processes for the manufacture of latex gloves is incomplete. It represents the methodology involved in shelf life determinations which are contemplated by the above referenced docket and is essential in order to properly comment on the state of technology so that compliance with the guidance can be assured. FDA was to present the final results to ASTM in December, 1999.
3. Guidance is released for public comment to provide a meaningful input of the manufacturers into the regulations. Without having complete information which will not be available until substantially after the deadline for comments, the release for public comment is not meaningful, and contrary to forming good public policy.

On the basis indicated above, we respectfully request that an extension for comments be granted until January 31, 2000. Thank you.

Sincerely,
CUSTOM SERVICES INTERNATIONAL INC.


Lillie C. Thomas, M.S.
Vice President of Quality Assurance and Regulatory Compliance

99D-2335

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EXT 1